

### **Amendments to the Claims:**

Please amend claims 25, 28, 34, and 40 as shown below. Please cancel claim 53. This listing of claims will replace all prior versions, and listings, of claims in the application.

Claims 1 to 24 (cancelled by way of the preliminary amendment filed November 25, 2001).

Claim 25 (currently amended): A method of producing a product according to a process essentially controlled by a set of  $n$  parameters  $X_i$  affecting a set of  $k$  properties  $Y_j$  characterizing the product, in which process at least some of said parameters  $X_i$  involved exhibit interfering effects on the desired properties  $Y_j$ , said method comprising:

- i) identifying an expected operational range of said process within which an optimal parameter value is likely to be found for each of said set of parameters  $X_i$ , and selecting given parameter data for obtaining experimentally associated property data;
- ii) assigning values to a set of  $k$  property weights  $w_j$  representing relative importance of said properties  $Y_j$  for the characterization of said product;
- iii) establishing a property behavior mathematical relations for each one of said set of  $k$  properties  $Y_j$  characterizing the product, said relation giving estimated property values  $Ye_j$  for each said property  $Y_j$  in terms of said parameters  $X_i$  within said range from given parameter data and associated property data, ~~said given parameter data and associated property data being essentially statistically insufficient for the purposes of quantifying said property behavior mathematical relation in the case that said relation is to be used to find optimal parameter values for said process to be optimized for only one of said set of  $k$  properties  $Y_j$  characterizing the product;~~

iv) using said property weights  $w_j$  and said property behavior mathematical relations for said set of  $k$  properties  $Y_j$  characterizing the product to establish a goal function in terms of property weighted deviations between the estimated properties  $Y_{e_j}$  and corresponding specified goal values for said properties  $Y_j$ ;

v) minimizing the goal function to generate a set of  $n$  optimal parameter values for said parameters  $X_i$ , wherein said property behavior mathematical relations for said set of  $k$  properties  $Y_j$  characterizing the product are sufficient for the purposes of establishing said goal function; and

v) using said set of optimal parameter values in said process to produce said product.

Claim 26 (original): A method according to claim 25, wherein said product is a composition of matter, said set of optimal parameter values characterizing an optimal formulation for the composition.

Claim 27 (original): A method according to claim 26, wherein said product is a pharmaceutical product, said set of optimal parameter values characterizing an optimal formulation for the pharmaceutical product.

Claim 28 (currently amended): A method according to claim ~~25~~<sup>53</sup>, wherein the values for said property weights  $w_j$  are obtained using an algorithm based on an analytic hierarchy process.

Claim 29 (original): A method according to claim 28, wherein said given property data are obtained through a number  $l$  of experimental runs of said process using said given parameter data, each said run using a distinct set of values for said given parameter data.

Claim 30 (original): A method according to claim 29, wherein said number of experimental runs of said process each uses a selected distinct set of values for said parameters  $X_i$  covering substantially all extreme values within a chosen range of values for each one of said parameters  $X_i$ , wherein  $l$  is at least equal to  $n + 1$  and is substantially less than a number used in the Fractional Factorial Matrix method.

Claim 31 (original): A method according to claim 27, wherein the values for said property weights  $w_j$  are obtained using an algorithm based on an analytic hierarchy process.

Claim 32 (original): A method according to claim 31, wherein said given property data are obtained through a number  $l$  of experimental runs of said process using said given parameter data, each said run using a distinct set of values for said given parameter data.

Claim 33 (original): A method according to claim 32, wherein said number of experimental runs of said process each uses a selected distinct set of values for said parameters  $X_i$  covering substantially all extreme values within a chosen range of values for each one of said parameters  $X_i$ , wherein  $l$  is at least equal to  $n + 1$  and is substantially less than a number used in the Fractional Factorial Matrix method.

Claim 34 (currently amended): A method according to claim 2553, wherein said goal function is expressed as follows:

$$G(X_1, \dots, X_n) = \sum_{j=1}^k w_j^2 (Ye_j - O_j)^2$$

wherein  $O_j$  are said specified goal values for said properties  $Y_j$ .

Claim 35 (original): A method according to claim 34, wherein said minimizing step is performed by successive iterations of:

$$G(X_1, \dots, X_n) = \sum_{i=1}^k [f_i(X_1, \dots, X_n)]^2.$$

Claim 36 (original): A method according to claim 35, wherein said goal function is minimized according to one or more specified ranges  $(a_i, b_i)$  wherein  $a_i < X_i < b_i$  for one or more of said optimal parameter values.

Claim 37 (original): A method according to claim 25, further comprising the steps of:  
 performing experimentally said process using said set of optimal parameters values to obtain corresponding experimental values for said properties  $Y_j$ ;  
 ranking said set of optimal parameters values over predetermined alternative sets of parameters values for said  $X_i$ .

Claim 38 (original): A method according to claim 37, wherein said ranking step is performed using an algorithm based on an analytic hierarchy process.

Claim 39 (previously presented): A method according to claim 37, further including the step of:

incorporating said set of optimal parameters values and said corresponding experimental values for said properties  $Y_j$  respectively into said given parameter and associated property data;  
 repeating said steps iii) to v) to generate a new set of optimal parameters values for said parameters  $X_i$ .

Claim 40 (currently amended): A method of producing a product using optimized process parameter values, said process being essentially controlled by a set of  $n$  parameters  $X_i$  characterizing a formulation for said product,  ~~$n$  being greater than two,~~ said parameters  $X_i$  affecting a set of  $k$  properties  $Y_j$  characterizing the product, in

which process at least some of said parameters  $X_i$  involved exhibit interfering effects on the desired properties  $Y_j$ , said method comprising:

conducting a number of  $l$  of experimental runs of said process each using a selected distinct set of values for said parameters  $X_i$  covering substantially all extreme values within a chosen range of values for each one of said parameters  $X_i$ , wherein  $l$  is at least equal to  $n + 1$  and is substantially less than a number used in the Fractional Factorial Matrix method, said chosen range corresponding to an expected operational range of said process within which an optimal parameter value is likely to be found for each of said set of parameters  $X_i$ ;

measuring values for said properties  $Y_j$  characterizing the product in each of said  $l$  experimental runs, whereby parameter data and associated property data are obtained from said selected distinct set of values for said parameters  $X_i$  and said measured values for said properties  $Y_j$ , respectively;

determining an importance of said properties  $Y_j$  for the characterization of said product, comparing said importance of said properties  $Y_j$  relative to one another, and assigning values to a set of  $k$  property weights  $w_j$  representing a relative importance of said properties  $Y_j$  for the characterization of said product;

establishing property behavior mathematical relations giving estimated property values  $Ye_j$  for each said property  $Y_j$  in terms of said parameters  $X_i$  within said chosen range from said parameter data and associated property data;

using said property weights  $w_j$  and said property behavior mathematical relations for said set of  $k$  properties  $Y_j$  characterizing the product to establish a process goal function in terms of property weighted deviations between the estimated properties  $Ye_j$  and corresponding specified

goal values for said properties  $Y_j$ , wherein said property behavior mathematical relations for said set of  $k$  properties  $Y_j$  characterizing the product are sufficient for the purposes of establishing said goal function;  
 minimizing the process goal function to generate a set of optimal parameter values for said parameters  $X_i$ , and  
 producing said product using said optimized process parameter values  $X_i$  calculated in the previous step.

Claim 41 (original): A method according to claim 40, wherein said product is a pharmaceutical product, and said process is a formulation of said product.

Claim 42 (previously cancelled).

Claim 43 (previously presented): A method according to claim 41, wherein the values for said property weights  $w_j$  are obtained by an algorithm based on an analytic hierarchy process.

Claim 44 (original): A method according to claim 40, wherein  $l = n + 1$ .

Claim 45 (previously cancelled).

Claim 46 (original): A method according to claim 43, wherein  $l = n + 1$ .

Claim 47 (previously presented): A method according to claim 41, wherein said goal function is expressed as follows:

$$G(X_1, \dots, X_n) = \sum_{j=1}^k w_j^2 (Y_{e_j} - O_j)^2$$

wherein  $O_j$  are said specified goal values for said properties  $Y_j$ .

Claim 48 (original): A method according to claim 47, wherein said minimizing step is performed through successive iterations.

Claim 49 (original): A method according to claim 48, wherein said goal function is minimized according to one or more specified ranges  $(a_i, b_i)$  wherein  $a_i < X_i < b_i$  for one or more of said optimal parameters values.

Claim 50 (previously presented): A method according to claim 41, further comprising the steps of:

- performing experimentally said process using said set of optimal parameters values to obtain corresponding experimental values for said properties  $Y_j$ ;

- ranking said set of optimal parameters values over predetermined alternative sets of parameters values for said  $X_i$ .

Claim 51 (original): A method according to claim 50, wherein said ranking step is performed through an algorithm based on an analytic hierarchy process.

Claim 52 (previously presented): A method according to claim 41, further including the steps of:

- incorporating said set of optimal parameters values and said corresponding experimental values for said properties  $Y_j$  respectively into said given parameter and associated property data;

- repeating said steps of conducting, measuring, establishing, using and minimizing to generate a new set of optimal parameters values for said parameters  $X_i$ .

Claim 53 (cancelled).